

Working Document
Not for Implementation

Stability Data File

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Stability Data File Documentation

The Stability Data File contains the stability tests results, cursory product information and links to completed information needed to review stability data. The Stability Data File has three sections: *Declarations*, *Products* and *Stability Study* sections. The declarations provide reference to external files that allow the Stability Data File to be properly processed for review. The *Product* sections provide a specification (list of tests, acceptance criteria and reference to the analytical methodologies) used in the stability studies. The *Stability Study* sections provide the details of each sample and test point, description of the stability study, test results and references to the stability protocol and product details.

The Stability Data File is an ASCII character file (flat file) using Extensible Markup Language (XML) markup according to World Wide Web Consortium (W3C) version 1.0.

This documentation describes the XML *Declaration* first then the *Product* and *Stability Study* markup sections together. The *Product* and *Stability Study* sections include a detailed description of each element and attribute that is allowed. The pattern of the elements and attributes, their names and in some cases the value of attributes are defined by a Document Type Definition (DTD). The DTD is provided after the elements and attributes description.

Declaration Section:

You should provide the declarations for the XML version, stylesheet (XSL) and document type definition (DTD) as the first three lines of the Stability Data File. Your declaration should be the same as the one provided below, each line starts with the "less than" sign ("<"):

```
<?xml version='1.0'?>
<?xml:stylesheet type="text/xsl"
href="http://www.fda.gov/cder/regulatory/ersr/ctoc/Resource/QUALITY/stability
_v500.xsl"?>
<!DOCTYPE stability SYSTEM
"http://www.fda.gov/cder/regulatory/ersr/ctoc/Resource/QUALITY/quality_V500
.dtd">
```

Product and Stability Study Sections:

The *Product* sections and the *Stability Study* sections are composed of XML elements and attributes that contain the information that are processed for presentation to the stability data reviewer. The Stability Data File identifies a product by its identification code and its specification. Each *Product* section can have multiple *Stability Study* sections identified by their lots, container closure systems, and storage conditions. The Stability Data File can contain multiple products. Table 1 contains a list of all the elements and attributes used in the Stability Data File *Product* and *Stability Study* sections. Following Table 1 each element and attribute is described in detail.

Table 1: Elements and attributes of the Stability Data File

<element> or “attribute”	Comment
"link"	Attribute to provide a hyperlink for any element
<stability>	Root element
<product>	Used for organizing one <i>Product</i> section
<productCode>	ID code for a product
<q6a_specification>	Used for organizing multiple sets of tests, acceptance criteria and analytical methodologies in the specification section
<specificationCode>	ID code for a single set of tests, their acceptance criteria and analytical methodologies
<specification>	Used for organizing a single test its acceptance criteria and its analytical methodology
“specID”	ID code for a single test, its acceptance criteria and its analytical methodology
<test>	Name for a single test
<criteria>	Numerical value for a single criterion
“unit”	Unit of measure for <criteria> numeral
“type”	Type of criteria (i.e., NMT, NLT, MT, LT, match)
<method>	Analytical procedure name for the <test> element in this <specification> element
<lot>	Used to organize stability data for a batch or lot
<lotNum>	ID for a single batch or lot
<packageCode>	ID for a single packaging presentation
<description>	Short description of the packaging
<fillSize>	Number of dosage units in this packaging
<protocolCode>	ID for the stability protocol describing this stability study
<storage>	Stability storage conditions
<orientation>	Position of the sample while on stability
<studyNum>	ID for this stability study
<startDate>	Date this stability study started
<expireDating>	Expiration dating, numerical value
“unit”	Expiration dating, time units
<analysis>	Used for organizing purposes
<sample>	Sample time point, numerical value
“unit”	Sample time point, time units
“sampleDate”	Date of the sample time point
<data>	Test result, numerical value
“unit”	Test result, unit of measure
“testDate”	Date this test was performed
“specID”	Reference to <specification> element’s “specID”
“type”	Type of test result (e.g., NMT, less than, etc.)
<note>	Used to organize the sponsor’s comments
<item>	Contains a single comment

Each of these elements and attributes is described below:

"link" attribute

The "link" attribute provides the ability to hyperlink to other files in the application. It contains the relative path and filename of the hyperlink target and can be used with any element. You should provide a completed link attribute to a file with detailed information for the <method>, <productCode>, <packageCode>, <protocolCode>, <specificationCode> and <lotNum> data elements. You can find more information about this where these individual elements are discussed later in this document.

<stability> element

The <stability> element is the root element. You should make it the first element and its end tag, </stability>, should be the last tag in the Stability Data File. It contains only the <product> element(s) and its child elements.

<product> element

You should provide a <product> element for each product (i.e. formulation, strength and dosage form) included in the Stability Data File. The <product> element should contain the <productCode>, <q6a_Specification> and <lot> elements and their child elements and attributes. You should provide one <productCode> element and one <q6a-specification> as child elements of the <product> element. You may provide as many <lot> elements as needed as discussed later in this document.

<productCode> element

You should provide one <productCode> element as a child element of the <product> element. The contents of the <productCode> element should be a unique identification of the product for which you are reporting stability. You should provide a "link" attribute with the <productCode> element that provides the relative path and filename to a file containing a summary of the product to which this unique code refers. The summary should be a small table that is contained on a single page. The summary should include the proprietary name, generic name, dosage form, route of administration, strength, color, type of package and number of dosage units in the package.

<q6a_specification> element

You should provide one <q6a-Specification> element as a child element of each <product> element. The <q6a_Specification> element contains the tests, references to analytical procedures, and acceptance criteria used to assess the stability sample(s). The <q6a-Specification> element contains one <specificationCode> element, one or more <specification> elements and their child elements and attributes.

<specificationCode> element

You should provide one <specificationCode> element as a child element of each <q6a_specification> element. The <specificationCode> element should contain a unique identification of the set of tests, acceptance criteria, and analytical methods used for this Stability Study in the Stability Data File. You should provide a "link" attribute with the <specificationCode> element that provides the relative path and filename to a file containing any additional information there may be about the specification.

<specification> element

You should provide <specification> elements for each <q6a_specification> element. There is no limit to the number of <specification> elements allowed as children of a <q6a_Specification> element. The <specification> element contains the information about a single test (test name, acceptance criteria and reference to the analytical procedure). The <specification> element contains in its child elements a single test name, reference to its analytical procedure (by hyperlink), and its acceptance criteria. The <specification> element should contain one <test> element, one <criteria> element, and one <method> element and the element attributes. You should provide a "specID" attribute for each <specification> element.

<specification> element "specID" attribute

You should provide a "specID" attribute for each <specification> element. The "specID" attribute provides a reference to a single test described by the <specification> element. You should provide a unique value for each <specification> element "specID" attribute value in the Stability Data File. The <specification> element's "specID" attribute is referenced by the <data> element's "specID" attribute described later in this document.

<test> element

You should provide one <test> element as a child element of the <specification> element. The <test> element should contain the name of the test being described (e.g. appearance, assay, dissolution, etc.)

<criteria> element

You should provide one or two <criteria> elements as a child elements of the <specification> element. The <criteria> element should contain one numerical value for one limit of the acceptance criteria range or the narrative specification. If there are two limits for the acceptance criteria range (e.g. 90-110%), you should provide two <criteria> elements. If there is one limit for the acceptance criteria (e.g. NMT 0.1%) or a narrative acceptance criteria, you should provide one <criteria> element. You should provide a "unit" attribute and a "type" attribute for each <criteria> element.

<criteria> element "unit" attribute

You should provide a "unit" attribute for each <criteria> element. The <criteria> element's "unit" attribute should have a value that describes the unit of measure for the content of the <criteria> element (e.g. %, mg, mcg, etc.). You can provide any value here that is needed. If no "unit" attribute is appropriate (e.g. narrative criteria), you should provide a "unit" attribute that has no value (i.e. <criteria unit="" >).

<criteria> element "type" attribute

You should provide a "type" attribute for each <criteria> element. You should provide a value for the <criteria> element's "type" attribute to describe certain types of data such as those with narrative test criteria and test results (e.g. appearance tests) and those with limit specifications (e.g. impurity and assay tests). The value for the "type" attribute is limited to a short list of valid values. The valid "type" attribute values are "match", "NMT", "NLT", "LT", and "MT". The correct use of each is described below:

<criteria type="match">

You should provide the value "match" when the criteria being provided is a narrative description and has no numerical value (e.g. appearance, shape, etc.) in the <criteria> element.

<criteria type="NMT">

You should provide the value "NMT" when the criteria being provided has an upper limit that includes the numerical value contained in the <criteria> element.

<criteria type="LT">

You should provide the value "LT" when the criteria being provided has an upper limit that does not include the numerical value contained in the <criteria> element.

<criteria type="NLT">

You should provide the "NLT" when the criteria being provided has a lower limit that includes the numerical value contained in the <criteria> element.

<criteria type="MT">

You should provide the value "MT" when the criteria being provided has a lower limit that does not include the numerical value contained in the <criteria> element.

<method> element

You should provide one <method> element as a child element of each <specification> element. The <method> element should contain the name of the analytical procedure used for the test described by the <specification> element. You should provide a "link" attribute for the <method> element that has a value of the relative path and filename to a file containing the complete analytical procedure.

<lot> element

You should provide a <lot> element for each batch, lot or portion of batch or lot that is included in the Stability Data File. The <lot> element contains a single stability study. The <lot> element contains only the <lotNum>, <packageCode>, <description>, <fillSize>, <protocolCode>, <storage>, <orientation>, <studyNum>, <startDate>, <expireDating>, and <analysis> elements and their child elements and attributes. You may provide many <lot> elements as child elements of a <product> element. You should not allow an additional <lot> element to start before the previous <lot> element is completed with the </lot> end tag.

<lotNum> element

You should provide one <lotNum> element as a child element of each <lot> element. The <lotNum> element contains the unique identification for this batch, lot or portion of batch or lot that is the subject of this stability study. You should provide a "link" attribute with the <lotNum> element that provides the relative path and filename to a file containing a summary of information relevant to this batch, lot or portion of batch or lot. The information should include the relationship to other batches and lots, clinical trials, biobatches, manufacturing method, etc.

<packageCode> element

You should provide one <packageCode> element as a child element of each <lot> element. The <packageCode> element contains the unique identification for the container closure system used for this batch, lot or portion of batch or lot. You should provide a "link" attribute with the <packageCode> element that provides the relative path and filename to a file containing a summary of the relevant container closure system. The summary should include a table containing the unique identification of the container closure system, a brief description, and a list of components. The list of components should include the part number, material of construction, function, dimension, source, drug master file reference, and code of federal regulations reference for each component.

<description> element

You should provide one <description> element as a child element of each <lot> element. The <description> element should contain a brief description of the

container closure system that is used in this stability study (e.g., 250 mL, white HDPE, CRC).

<fillSize> element

You should provide one <fillSize> element as a child element of each <lot> element. The <fillSize> element should contain the number of dosage units, volume, weight or some other indication the amount of product in each container closure system that is being included in the stability study (e.g., 10 mL, 75 tablets).

<protocolCode> element

You should provide one <protocolCode> element as a child element of each <lot> element. The <protocolCode> element contains the unique identification for the stability protocol used to create the data in this Stability Study. You should provide a "link" attribute with the <protocolCode> element that provides the relative path and filename to the stability study protocol file.

<storage> element

You should provide one <storage> element as a child element of each <lot> element. The <storage> element contains the storage condition for the samples in this Stability Study. You should provide the temperature range and humidity.

<orientation> element

You should provide one <orientation> element as a child element of each <lot> element. The <orientation> element contains the orientation of the samples used to create the data in this Stability Study (e.g. upright).

<studyNum> element

You should provide one <studyNum> element as a child element of each <lot> element. The <studyNum> element contains the unique identification for this Stability Study or portion of a Stability Study. If a portion of the data was previously submitted, you should provide a "link" attribute for the <studyNum> element. You should give the "link" attribute a value that is the relative path and filename of the relevant Stability Data File that was previously submitted.

<expireDating> element

You should provide one <expireDating> element as a child element of each <lot> element. The <expireDating> element should contain the numerical value of the expiration dating period for the sample used to create the data in this Stability Study. It should not contain the unit of measure for the expiration dating period. For example, the correct <expireDating> element content for a 24 month expiration dating period is 24. You should provide a "unit" attribute for each <expireDating> element as described below:

<expireDating> element "unit" attribute

You should provide one "unit" attribute for each <expireDating> element. The <expireDating> element's "unit" attribute should have a value that describes the units of measure for the expiration dating period. You should provide one of the following values for the <expireDating> element's "unit" attribute: second, minute, hour, day, month, or year.

<analysis> element

You should provide <analysis> elements as child elements of each <lot> element. The <analysis> element contains the test results for each test done at a sampling time point. You should provide an <analysis> element for each time point that was sampled in this stability study. The <analysis> element contains only the <sample> and <data> elements and their attributes.

<sample> element

You should provide one <sample> element as a child element of each <analysis> element. The <sample> element contains the numerical value of the sample time point this data represents. For example, the correct <sample> element content for the 12-month sample is 12. The <sample> element also contains the "unit" attribute and the "sampleDate" attribute both described below:

<sample> element "unit" attribute

You should provide a "unit" attribute for each <sample> element. The <sample> element's "unit" attribute should have a value that describes the units of measure for the content of the <sample> element. The value for the <sample> element's "unit" attribute should be one of the following: second, minute, hour, day, month, year. You should use the same <sample> element "unit" attribute value for all the <sample> elements in a stability study.

<sample> element "sampleDate" attribute

You should provide a "sampleDate" attribute for each <sample> element. The <sample> element's "sampleDate" attribute should have a value that is the sample date in a year-month-day format. The year should be first using 4 digits followed by a dash. The month is second using 2 digits followed by a dash. The day is third using two digits. For example, a sample that you removed from the stability storage conditions on January 9, 2001, should have a <sample> element "sampleDate" attribute value of 2001-01-09.

<data> element

You should provide a <data> element for each data point within this <sample> element. The <data> element contains the numerical value for one test result being reported. For example, the correct <data> element content for a test result of 95.0% is 95.0. There is no limit on decimal places or the number of digits. You should also provide a "unit" attribute, "testDate" attribute and "specID"

attribute for each <data> element. You may provide a "type" attribute for each <data> element. These are described later under this element heading.

You may want to provide more than one data point for sample test results (e.g., dissolution, retests according to allowed procedure, etc.). For this case, you should list the additional test results by simply repeating the <data> element and its attribute values on additional lines. You then provide each additional test result as the content of one of the additional lines. This is described in detail in the Example Stability Data File section.

<data> element "unit" attribute

You should provide a "unit" attribute for each <data> element. The <data> element's "unit" attribute should have a value that describes the units of measure for the content of the <data> element (e.g. %, mg, mcg, etc.). You can provide any value here that is needed. You should use the same <data> element "unit" attribute value for <data> elements with the same "specID" attribute value. For example, you should not report one assay result in percent and at another sample time point report the same test with results in milligrams.

<data> element "testDate" attribute

You should provide a "testDate" attribute for each <data> element. The <data> element's "testDate" attribute should have a value that is the sample date in a year-month-day format. The year should be first using 4 digits followed by a dash. The month is second using 2 digits followed by a dash. The day is third using two digits. For example, a sample that you tested on May 11, 2001 should have a <data> element "testDate" attribute value of 2001-05-11.

<data> element "specID" attribute

You should provide a "specID" attribute for each <data> element. The <data> element's "specID" attribute should have a value that is the same as one of the parent <specification> element's "specID" attributes.

<data> element "type" attribute

You may provide a "type" attribute for each <data> element for which it is appropriate. You should provide a value for the <data> element's "type" attribute to describe certain types of data when appropriate. For example, a limit test may have a <data> element "type" attribute value of "NMT" or "not more than". The value for the "type" attribute is not limited.

<note> element

You may provide one <note> element as a child element of a <lot> element where it is appropriate. The <note> element is used to organize comments about the

stability study contained in <item> elements. The <note> element contains <item> elements.

<item> element

You may provide <item> elements as child elements of a <note> element. There is no limit to the number of <item> elements or their content. The <item> element contains the comments you may wish to provide for the stability report (e.g., drug substance use for clinical study, biobatch, etc.). If you wish to provide a comment that is more than a sentence or to, you should provide a shorter comment and provide a "link" attribute for the <item> element. The "link" attribute should contain the relative path and filename for a file that contains the full comment.

Stability Data File DTD

```
1      <!-- DTD Stability Data File 2001-05-04-->
2      <!ELEMENT stability (product+)>
3      <!ELEMENT product      (productCode, q6a_specification, lot+)>
4          <!ELEMENT productCode (#PCDATA)>
5              <!ATTLIST productCode      link CDATA #REQUIRED
6                  submissionCode CDATA #IMPLIED>
7      <!ELEMENT q6a_specification (specificationCode, specification+)>
8          <!ELEMENT specificationCode (#PCDATA)>
9              <!ATTLIST specificationCode      link CDATA #REQUIRED
10                  submissionCode CDATA #IMPLIED>
11      <!ELEMENT specification (test, criteria+, method)>
12          <!ATTLIST specification specID ID #REQUIRED>
13      <!ELEMENT test (#PCDATA)>
14          <!ATTLIST test      link CDATA #IMPLIED
15                  submissionCode CDATA #IMPLIED>
16      <!ELEMENT criteria (#PCDATA)>
17          <!ATTLIST criteria      link CDATA #IMPLIED
18                  submissionCode CDATA #IMPLIED
19                  unit CDATA #REQUIRED
20                  type (LT|MT|NLT|NMT|match) #REQUIRED>
```

```
<!ELEMENT method (#PCDATA)>
  <!ATTLIST method  link CDATA #REQUIRED
                    submissionCode CDATA #IMPLIED>
```

```
<!ELEMENT lot      (lotNum,
                    packageCode,
                    description,
                    fillSize,
                    protocolCode,
                    storage,
                    orientation,
                    studyNum,
                    startDate,
                    expireDating,
                    analysis+, note?)>
```

```
<!ELEMENT lotNum (#PCDATA)>
  <!ATTLIST lotNum  link CDATA #REQUIRED
                    submissionCode CDATA #IMPLIED>
```

```
<!ELEMENT packageCode (#PCDATA)>
  <!ATTLIST packageCode  link CDATA #REQUIRED
                        submissionCode CDATA #IMPLIED>
```

```
<!ELEMENT description (#PCDATA)>
  <!ATTLIST description  link CDATA #IMPLIED>
```

```
43         submissionCode CDATA #IMPLIED>
44     <!--ELEMENT fillSize (#PCDATA)>
45         <!--ATTLIST fillSize    link CDATA #IMPLIED
46             submissionCode CDATA #IMPLIED>
47     <!--ELEMENT protocolCode (#PCDATA)>
48         <!--ATTLIST protocolCode    link CDATA #REQUIRED
49             submissionCode CDATA #IMPLIED>
50     <!--ELEMENT storage (#PCDATA)>
51         <!--ATTLIST storage    link CDATA #IMPLIED
52             submissionCode CDATA #IMPLIED>
53     <!--ELEMENT orientation (#PCDATA)>
54         <!--ATTLIST orientation    link CDATA #IMPLIED
55             submissionCode CDATA #IMPLIED>
56     <!--ELEMENT studyNum (#PCDATA)>
57         <!--ATTLIST studyNum    link CDATA #IMPLIED
58             submissionCode CDATA #IMPLIED>
59     <!--ELEMENT startDate (#PCDATA)>
60         <!--ATTLIST startDate    link CDATA #IMPLIED
61             submissionCode CDATA #IMPLIED>
62     <!--ELEMENT expireDating (#PCDATA)>
63         <!--ATTLIST expireDating    link CDATA #IMPLIED
64             submissionCode CDATA #IMPLIED>
```



```
65                                     unit (second|minute|hour|day|month|year) #REQUIRED>
66 <!--ELEMENT analysis (sample, data+)-->
67   <!--ELEMENT sample (#PCDATA)-->
68     <!--ATTLIST sample    link CDATA #IMPLIED
69                           submissionCode CDATA #IMPLIED
70                           unit (second|minute|hour|day|month|year) #REQUIRED
71                           sampleDate CDATA #REQUIRED-->
72   <!--ELEMENT data (#PCDATA)-->
73     <!--ATTLIST data      link CDATA #IMPLIED
74                           submissionCode CDATA #IMPLIED
75                           unit CDATA #REQUIRED
76                           testDate CDATA #REQUIRED
77                           specID IDREF #REQUIRED
78                           type CDATA #IMPLIED-->
79   <!--ELEMENT note (item+)-->
80     <!--ELEMENT item (#PCDATA)-->
81       <!--ATTLIST item    link CDATA #IMPLIED
82                           submissionCode CDATA #IMPLIED-->
83
84 <!--The "submissionCode" attribute is reserved for future use to simplify hyperlinks-->
85 <!-- Created by: Naiqi Ya on 2000-01-06 last functional edit on 2001-01-18 -->
86 <!-- Jon Clark StandAlone edit 2001-04-27-->
```

Example Stability Data File and Special Cases

The example Stability Data File provided here is for a single product, single stability study for a single lot, batch or portion of lot or batch (lot). It is provided here for illustration purposes to further clarify the arrangement of elements and attributes in the Stability Data File. Each paragraph below discusses a special case and refers to a line number in the example Stability Data File.

Multiple Test Results for the Same Test

You may want to provide more than one data point for sample test results (e.g., dissolution, retests according to allowed procedure, etc.). For this case, you should list the additional test results by simply repeating the <data> element and its attribute values on additional lines. You then provide each additional test result as the content of one of the additional lines. This is shown in the example at lines 57-69, 72-73, 80-91, 100-110 and 120-131.

Multiple Products in the Same Stability Data File

You may want to provide stability data for multiple products in the same Stability Data File. To do this you should repeat the <product> element and all its contents after the previous <product> element's end tag, </product>. In this example, the next product would start at line 143.

Multiple Lots for the Same Product

You may want to provide another lot for the same product without repeating the product identification and the specification. To do this you should repeat the <lot> element and all its contents after the previous <lot> element's end tag, </lot>. In this example, the next lot would start at line 141.

Multiple Stability Study Data Reports for the Same Product and Same Stability Protocol

This is the same as providing additional stability study data reports for the same lot number. This sometimes occurs with matrix studies where various container closure systems are studied at one time. To do this you repeat the <lot> element and all its contents (with the changed packaging information) after the previous <lot> element's end tag, </lot>. The new data's <lot> element would begin at line 141.

Duplicate Stability Study with New Test Results

You may want to provide results from a duplicate stability study on the same product lot and container closure system. To do this you repeat the <lot> element and all its contents after the previous <lot> element's end tag, </lot>. The duplicate report would begin at line 141.

Explanation for an Unexpected Test Result

You may want to provide an explanation of an unexpected test result. To do this you should provide a "link" attribute with the <data> element that contains the test result. You should provide a value for the "link" attribute that is the relative path and filename for a document that provides the information you wish to associate with the test result. This occurs in the example at lines 66-67 and 70-71.

Comments about a Stability Study

You may want to provide comments about a stability study. To do this you should provide a <note> element and an <item> element. You should provide the comment in the <item> element and place the <item> element in the <note> element. You can provide additional <item> elements inside the <note> element. If the comment is more than a few lines, you should provide a "link" attribute for the <item> element. You should provide a value for the "link" attribute that is the relative path and filename for a document that provides the information you wish to associate with the stability study. An example of the <item> element occurs on line 138.

Data a Previously Submitted Stability Data File

You may be submitting data for only the final portion of a stability study. If a portion of the data was previously submitted, you should provide a "link" attribute for the <studyNum> element. You should give the "link" attribute a value that is the relative path and filename of the relevant Stability Data File that was previously submitted. Avoid sending duplications of previously submitted data. The <studyNum> element in the example is on line 52.

Declaration Paths and Filenames

The XML declarations are on lines 1, 2 and 3. Part of the declaration contains the Internet paths and filenames for the stylesheet and DTD. These files are used to process the Stability Data File for the stability data reviewer. You should use the following declaration paths and filenames when submitting the Stability Data File for review by the Agency:

http://www.fda.gov/cder/regulatory/ersr/ctoc/Resource/QUALITY/stability_v500.xsl

http://www.fda.gov/cder/regulatory/ersr/ctoc/Resource/QUALITY/quality_v500.dtd

If you wish to use a different stylesheet and DTD or the same ones in a different location, you should use the path and filename or relative path and filename for files you wish to reference. An example of this is if you successfully downloaded the working model for the Stability Data File and want to replace the demonstration data with your own. To do this you would paste your Stability Data File into the working model and use the relative path and filenames used by the Stability Data File in the working model.

Blank Lines in the Stability Data File

Blank lines in the Stability Data File have no affect on the file or its processing. You can see examples of blank lines at lines 140, 143 and 145.

Stability Data File

The sample Stability Data File begins on the next page:

Draft

```
1      <?xml version='1.0'?>
2      <?xml:stylesheet type="text/xsl"
3      href="http://www.fda.gov/cder/regulatory/ersr/ctoc/Resource/QUALITY/stability_v500.xsl"?>
4      <!DOCTYPE stability SYSTEM "http://www.fda.gov/cder/regulatory/ersr/ctoc/Resource/QUALITY/quality_v500.dtd">
5      <stability>
6          <product>
7              <productCode link="../0004/P1_Overview.PDF">Cureall 100</productCode>
8              <q6a_specification>
9                  <specificationCode link="../0000/ST-SPEC 001.pdf">ST-SPEC 001</specificationCode>
10                 <specification specID="Spec001" >
11                     <test>Description</test>
12                     <criteria type="match" unit="">White film-coated, modified capsule shaped, biconvex, beveled
13                     edge tablet debossed with 001 on one side and WD on the other side.</criteria>
14                     <method link="../0000/VP001-2.pdf">Visual</method>
15                 </specification>
16                 <specification specID="Spec002">
17                     <test>Drug release</test>
18                     <criteria type="NLT" unit="">20</criteria>
19                     <criteria type="NMT" unit="" in one hour">55</criteria>
20                     <method link="../0000/P5.2_Dissolution_Procedures.pdf">FP001-2</method>
21                 </specification>
22                 <specification specID="Spec003">
```

```
23      <test>Drug release</test>
24      <criteria type="NLT" unit="% in four hours">80</criteria>
25      <method link="..\0000\P5.2_Dissolution_Procedures.pdf">FP001-2</method>
26    </specification>
27    <specification specID="Spec004">
28      <test>Assay</test>
29      <criteria type="NLT" unit="%">95.0</criteria>
30      <criteria type="NMT" unit="%">105.0</criteria>
31      <method link="..\0000\P5.2_Assay_Procedure.pdf">FP001-4</method>
32    </specification>
33    <specification specID="Spec005">
34      <test>Single impurity</test>
35      <criteria type="NMT" unit="%">1.0</criteria>
36      <method link="..\0004\P5.2_Impurity_Procedures.pdf">FP001-5</method>
37    </specification>
38    <specification specID="Spec006">
39      <test>Total impurities</test>
40      <criteria type="NMT" unit="%">2.0</criteria>
41      <method link="..\0004\P5.2_Impurity_Procedures.pdf">FP001-5</method>
42    </specification>
43  </q6a_specification>
44  </lot>
```

<lotNum link="../0004/ProductionOverview.PDF">WD001A</lotNum>
<packageCode link="../0004/ContainerClosure.PDF">PK001</packageCode>
<description>100 mL white opaque round HDPE bottle with 38 mm CRC cap</description>
<fillSize>100 tablets</fillSize>
<protocolCode link="../0000/StabilityProtocol.pdf">Pre-approval stability Protocol</protocolCode>
<storage>40 ± 2°C/75 ± 5%RH</storage>
<orientation>Upright</orientation>
<studyNum>STS001A</studyNum>
<startDate>2000-01-01</startDate>
<expireDating unit="month">24</expireDating>
<analysis>
 <sample sampleDate="1999-12-28" unit="month">0</sample>
 <data specID="Spec001" testDate="2000-01-01" unit="">Conformed</data>
 <data specID="Spec002" testDate="2000-02-05" unit="">48.0</data>
 <data specID="Spec002" testDate="2000-02-05" unit="">44.0</data>
 <data specID="Spec002" testDate="2000-02-05" unit="">48.6</data>
 <data specID="Spec002" testDate="2000-02-05" unit="">49.9</data>
 <data specID="Spec002" testDate="2000-02-05" unit="">48.9</data>
 <data specID="Spec002" testDate="2000-02-05" unit="">43.4</data>
 <data specID="Spec002" testDate="2000-02-05" unit="">49.1</data>
 <data specID="Spec002" testDate="2000-02-05" unit="">48.8</data>
 <data specID="Spec002" testDate="2000-02-05" unit="">50.0</data>

67 <data specID="Spec002" testDate="2000-02-05" unit="%"
68 link="DataPointExplanation1.pdf">55.5</data>
69 <data specID="Spec002" testDate="2000-02-05" unit="%">44.8</data>
70 <data specID="Spec002" testDate="2000-02-05" unit="%">40.9</data>
71 <data specID="Spec003" testDate="2000-01-02" unit="%"
72 link="DataPointExplanation2.pdf">93</data>
73 <data specID="Spec004" testDate="2000-01-03" unit="%">98.2</data>
74 <data specID="Spec004" testDate="2000-01-03" unit="%">99.201</data>
75 <data specID="Spec005" testDate="2000-01-03" type="LT" unit="%">0.1</data>
76 <data specID="Spec006" testDate="2000-01-03" unit="%">0.4</data>
77 </analysis>
78 <analysis>
79 <sample sampleDate="2000-01-29" unit="month">1</sample>
80 <data specID="Spec001" testDate="2000-02-01" unit="">Conformed</data>
81 <data specID="Spec002" testDate="2000-03-05" unit="%">38.5</data>
82 <data specID="Spec002" testDate="2000-03-05" unit="%">42.5</data>
83 <data specID="Spec002" testDate="2000-03-05" unit="%">43.5</data>
84 <data specID="Spec002" testDate="2000-03-05" unit="%">40.3</data>
85 <data specID="Spec002" testDate="2000-03-05" unit="%">42.2</data>
86 <data specID="Spec002" testDate="2000-03-05" unit="%">42.4</data>
87 <data specID="Spec002" testDate="2000-03-05" unit="%">43.2</data>
88 <data specID="Spec002" testDate="2000-03-05" unit="%">42.6</data>

89 <data specID="Spec002" testDate="2000-03-05" unit="%">45.7</data>
90 <data specID="Spec002" testDate="2000-03-05" unit="%">36.3</data>
91 <data specID="Spec002" testDate="2000-03-05" unit="%">42.0</data>
92 <data specID="Spec002" testDate="2000-03-05" unit="%">44.2</data>
93 <data specID="Spec003" testDate="2000-02-01" unit="%">96</data>
94 <data specID="Spec004" testDate="2000-02-01" unit="%">97.1</data>
95 <data specID="Spec005" testDate="2000-02-03" unit="%">0.1</data>
96 <data specID="Spec006" testDate="2000-02-03" unit="%">0.4</data>
97 </analysis>
98 <analysis>
99 <sample sampleDate="2000-02-20" unit="month">2</sample>
100 <data specID="Spec001" testDate="2000-02-24" unit="">Conformed</data>
101 <data specID="Spec002" testDate="2000-04-05" unit="%">42.7</data>
102 <data specID="Spec002" testDate="2000-04-05" unit="%">42.1</data>
103 <data specID="Spec002" testDate="2000-04-05" unit="%">41.7</data>
104 <data specID="Spec002" testDate="2000-04-05" unit="%">47.0</data>
105 <data specID="Spec002" testDate="2000-04-05" unit="%">48.5</data>
106 <data specID="Spec002" testDate="2000-04-05" unit="%">44.9</data>
107 <data specID="Spec002" testDate="2000-04-05" unit="%">45.9</data>
108 <data specID="Spec002" testDate="2000-04-05" unit="%">49.7</data>
109 <data specID="Spec002" testDate="2000-04-05" unit="%">42.0</data>
110 <data specID="Spec002" testDate="2000-04-05" unit="%">41.1</data>

111 <data specID="Spec002" testDate="2000-04-05" unit="%">49.2</data>
112 <data specID="Spec002" testDate="2000-04-05" unit="%">48.1</data>
113 <data specID="Spec003" testDate="2000-02-24" unit="%">92</data>
114 <data specID="Spec004" testDate="2000-02-24" unit="%">97.5</data>
115 <data specID="Spec005" testDate="2000-02-25" unit="%">0.1</data>
116 <data specID="Spec006" testDate="2000-02-25" unit="%">0.5</data>
117 </analysis>
118 <analysis>
119 <sample sampleDate="2000-03-27" unit="month">3</sample>
120 <data specID="Spec001" testDate="2000-03-30" unit="">Conformed</data>
121 <data specID="Spec002" testDate="2000-05-05" unit="%">46.5</data>
122 <data specID="Spec002" testDate="2000-05-05" unit="%">43.9</data>
123 <data specID="Spec002" testDate="2000-05-05" unit="%">41.7</data>
124 <data specID="Spec002" testDate="2000-05-05" unit="%">36.8</data>
125 <data specID="Spec002" testDate="2000-05-05" unit="%">36.2</data>
126 <data specID="Spec002" testDate="2000-05-05" unit="%">42.0</data>
127 <data specID="Spec002" testDate="2000-05-05" unit="%">36.7</data>
128 <data specID="Spec002" testDate="2000-05-05" unit="%">43.2</data>
129 <data specID="Spec002" testDate="2000-05-05" unit="%">43.4</data>
130 <data specID="Spec002" testDate="2000-05-05" unit="%">43.4</data>
131 <data specID="Spec002" testDate="2000-05-05" unit="%">43.4</data>
132 <data specID="Spec002" testDate="2000-05-05" unit="%">34.5</data>

```
133      <data specID="Spec003" testDate="2000-03-31" unit="%">94</data>
134      <data specID="Spec004" testDate="2000-03-31" unit="%">96.8</data>
135      <data specID="Spec005" testDate="2000-03-31" unit="%">0.2</data>
136      <data specID="Spec006" testDate="2000-03-31" unit="%">0.5</data>
137    </analysis>
138    <note>
139      <item>This is for demo purpose only.</item>
140
141    </note>
142  </lot>
143
144  </product>
145
146</stability>
147<!-- Stability XML File -->
148<!-- Created by: Naiqi Ya on 2000-01-06 last functional edit on 2001-04-30-->
149<!-- Jon Clark StandAlone edit on 2001-05-02-->
```

Glossary:

attribute

An XML element (see glossary term "element") may have an attribute. The attribute is given a value inside the element's start tag (see glossary term "tag"). The attribute name occurs after the element name and one space. The attribute value occurs after the attribute name an equal sign (=) and within quotes (" "). If there is more than one attribute, the remaining attributes occur after the preceding attribute value's end quote (") and one space. The following example shows two attributes named one and two being given values of 1 and 2 respectively for the empty `<example>` element: `<example one="1" two="2"> </example>`. In this example the `<example>` element is said to "have" attribute one and attribute two. In the Stability Data File, the `<data>` element has the attributes "unit", "testDate", "specID" and "type".

The attribute names that can be given values within a particular element can be defined in a Document

Type Definition (DTD) (see glossary term "Document Type Definition"). Attribute values can be restricted to a list of values within the DTD (e.g. `<criteria>` element's "type" attribute). An attribute can have two different functions when it occurs in two different places. For example, the "type" attribute is restricted to a short list in the DTD when it occurs in the `<criteria>` element, but it can have any value when it occurs in the `<data>` element.

child element

An XML element (see glossary term "element") with a start tag (see glossary term "tag") and end tag between the start tag and end tag of another element is the child element. The element with the earlier start tag and later end tag is said to "contain" the child element. In the following example the `<parent>` element contains the empty `<child>` element: `<parent> <child> </child> </parent>`. In this example the `<child>` element has a lower hierarchical position than the `<parent>` element. In the Stability Data File, the `<specification>` element contains the `<test>`, `<criteria>` and `<method>` elements, so they are called child elements.

Document Type Definition (DTD)

The Stability Data File uses a Document Type Definition (DTD) to control the element hierarchy, element attributes and some attribute values. The rules governing XML allow the DTD to be part of the XML file or to be referenced in the declaration section of the XML file. The Stability Data File (an XML file) is designed to reference a DTD that is located outside the XML file. The reference is on the third line of the Stability Data File and is as follows:

```
<!DOCTYPE stability SYSTEM  
"http://cdemet/ONDC/CTOC/resource/quality/QUALITY-V500.dtd">
```

A copy of the DTD is provided as APPENDIX to this document.

element

Information in an XML file is divided into specific pieces. These pieces are called elements. The element name identifies the piece of information. Element names are bracketed using the special characters, "<" and ">". For example, the analytical procedure might be identified with the element named "method". This element appears in the Stability Data File as "<method>". Inside the XML document, the element name is placed just prior to the piece of information and after the information. The element is said to "contain" the piece of information. In the Stability Data File, the name of the "assay" analytical procedure would be tagged as follows <method>assay</method>. The / prior to the second element name denotes that this is the end of the information about the analytical procedure. In this example the content of the <method> element is "assay".

In the Stability Data File, elements can contain other elements in a hierarchical structure (see the glossary term "child element"). The element names and their hierarchical structure can be defined in a Document Type Definition (see glossary term "Document Type Definition").

root element

The first element in an XML file is the root element (see glossary term "element"). The first tag (see glossary term "tag") in the XML file is the root element's start tag and the last tag is the root element's end tag. All other elements and their element contents are contained within the root element.

Relative Path and Filename

You should use the relative path and filename as a value for the "link" attribute when you wish to create a hyperlink to another document (target file). When the target file is located in the same directory (folder) as the Stability Data File, the relative path and filename is simply the complete filename (with extension). When the target file is located in a different folder there is more than one case.

When the target file is in a different folder from the Stability Data File and the two folders are contained in the same parent folder, the relative path and filename is the complete filename preceded with either a forward slash (/) or back slash (\) preceded with the target file's folder name which is preceded by a series of three characters, two dots followed by either the back or forward slash (..\ or ../).

For example, the Stability Data File may have the following full path and filename: A:\0005\stability\report2.xml. The target file may have the following full path and filename: A:\0005\procedures\assay.pdf. The following value for

the "link" attribute value in the Stability Data File named report2.xml will create a hyperlink to the assay.pdf file: ../procedures/assay.pdf.

When the target file is in a different folder (e.g. a previously submitted file) the same procedure is used except that it is extended so the different folder levels are named, separated by either the back or forward slash and the value starts with as many iterations of "..\" or "../" as needed to step up to the nearest common folder.

For example, you may have previously submitted the target file named assay.pdf and it had the following path and filename in the previous submission:

A:\0000\procedures\assay.pdf. The following "link" attribute value in the Stability Data File mentioned above will create a hyperlink to the previously submitted assay.pdf file: ../../0000/procedures/assay.pdf.

stability study

A collection of test results for a batch, lot or portion of batch or lot in a specific storage conditions at measured time intervals. The storage condition specifications include temperature and humidity, container closure system (if any), and the orientation of the container closure system.

tag

An XML element (see glossary term "element") has two tags, the start tag and the end tag. The tag that begins the element with the element name prefixed with a "<" character and ending with a ">" character is the start tag. The tag that ends the element with the element name prefixed with the "</" characters and ending with the ">" character is the end tag. In the Stability Data File the end tag for the analytical procedure is "</method>"